



## **MMCC New Condition Approval Petition: Petitioner Guidance**

Pursuant to Health-General Article, §13–3304 and Code of Maryland Regulations (“COMAR”) 10.62.07, the Maryland Medical Cannabis Commission (the “MMCC”) is authorized to approve additional qualifying conditions that certifying providers are encouraged to treat with medical cannabis. The MMCC may add a qualifying condition if: (1) the medical condition is debilitating, (2) the pain, suffering, and disability of the medical condition can reasonably be expected to be relieved by medical cannabis; and (3) other medical treatments have proven ineffective in providing relief. COMAR 10.62.07.06. This guidance provides patients, providers, medical cannabis businesses, and other stakeholders with information on the petition process, including content requirements.

### **I. Petition Submission Process**

- 1) Any person may petition the MMCC to add a qualifying medical disease or condition to those listed in COMAR 10.62.03.01B.
- 2) The petition must use the form provided on the [MMCC website](#). Each petition shall be limited to one qualifying medical condition.
- 3) The petition shall include the following information:
  - a. Name of the condition, including its ICD-10 codes or Diagnostic and Statistical Manual of Mental Disorders (DSM) codes.
  - b. Description of the condition, including symptoms, disease progression and complications. Information about the prevalence of the condition and its complications should also be addressed.
  - c. Information about current treatment modalities for the medical condition, effectiveness, side effects.
  - d. Evidence that supports a finding that the use of medical cannabis provides a benefit to patients by alleviating pain, suffering, disability or symptoms of the medical condition. Evidence that will be accepted include:
    - i. Full text, published scientific studies in peer-reviewed journals (include citations and a summary of the studies);
    - ii. Randomized clinical trials; and
    - iii. Well-designed cohort and case-control studies.
  - e. Information or studies regarding any risks or adverse effects from the use of medical cannabis in patients with the medical condition that is the subject of the

petition. **Note:** The petition must demonstrate that an effort has been made to seek out information regarding potential harms or adverse effects related to the use of medical cannabis for the medical condition.

- f. Letters of support from physicians, other licensed health care professionals or researchers knowledgeable about the condition, treatment or disease.

## **II. Summary Denials of Petitions**

- 1) Petitions shall be summarily denied by the MMCC without submitting for public comment or public hearing, if the petition is facially insubstantial. A petition is facially insubstantial if:
  - a. The petition is incomplete or lacking information requested by the MMCC;
  - b. The medical condition identified in the petition is not a clinical condition recognized by the medical community at-large;
  - c. The petition involves, in whole or in part, a decision outside of the MMCC's legal or regulatory authority, as determined by the MMCC's counsel; or
  - d. The petition pertains to a medical condition, medical treatment or disease that has been previously considered and rejected by the MMCC, unless scientific evidence not previously considered is included in the new petition.
- 2) The MMCC will issue the denial, in writing, to the primary applicant listed in the petition form, with the reasons for the summary denial.
- 3) Petitions denied by the MMCC for public comment or public hearing due to the conditions outlined above may be resubmitted for consideration.
- 4) All complete petitions and supporting documentation will be reviewed by the Research Committee of the MMCC.

## **III. Petition Evaluation and Final Determination**

- 1) The MMCC Research Committee is responsible for:
  - a. Reviewing petitions submitted to add new qualifying medical conditions that certifying providers are encouraged to treat with medical cannabis; and
  - b. Compiling information relevant to the petition. Information may include:
    - i. An independent literature review with a summary of peer-reviewed scientific research studies related to both the potential benefits and adverse effects of the use of medical cannabis for the medical disease or condition.
    - ii. Consulting with one or more experts in cannabis therapeutics and experts on the medical disease or condition that is the subject of the petition.

2) Public Hearing: The Committee will hold a public hearing of the petition within 12 months of the receipt of the petition, and provide at least 30 days' notice to the public. The notice will include information about the date, time, location and a brief description of the petition(s) to be discussed at the public hearing. The purpose of the public hearing is for the Committee to consider whether the qualifying condition(s) should be added to COMAR 10.62.03.01B. As part of the hearing:

- a. The Committee may invite oral and written testimony from experts with experience in the clinical management of the medical condition or disease being proposed to be added as a qualifying medical condition; and
- b. The public is invited to submit written testimony in response to the petition up to 14 days after the hearing is held.

3) Research Committee Decision

- a. The Committee will vote to make a recommendation to approve or deny a petition based on:
  - i. Evidence compiled from available published scientific literature,
  - ii. Expert testimony, and
  - iii. Public comment.
- b. The Committee's deliberation will focus on whether there is reasonable evidence that:
  - i. Medical cannabis can be expected to provide benefit for patients with the medical condition;
  - ii. Any adverse effects or harm from using medical cannabis to treat the medical condition is outweighed by the benefits for patients with the medical condition; and
  - iii. Other available treatment modalities are ineffective in providing relief for patients with the medical condition.
- c. The Committee's written recommendation will be shared with the Chairperson for the MMCC. The recommendation will outline what the Committee considered in reaching its decision.

4) MMCC Decision

- a. The full Commission must consider the petition and the Committee's recommendation.
- b. The full Commission will consider the Committee's recommendation at an open meeting.
- c. The petition will be placed on the agenda of a subsequent Commission meeting for a discussion and vote by the full Commission.